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3RD TO 6TH
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World Federation for Hospital Sterilisation Sciences

Determination of the steam amount inside long, fine cavities

using absorption spectroscopy and computational fluid dynamics

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Overview

I. Background

II. Methods

- ➢ Absorption spectroscopy
- ➢ Computational fluid dynamics

III. Steam penetration in thin-walled channels

- ➢ Geometry – pipe
- ➢ Results – original 134 °C sterilization cycle
- ➢ Results – adapted 134 °C sterilization cycle

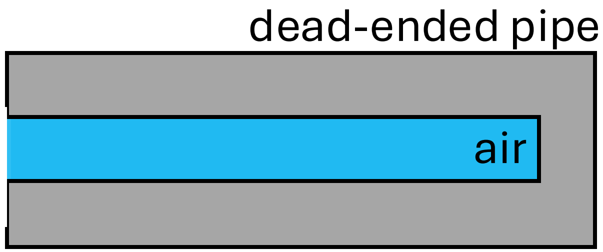
IV. Steam penetration in hollow devices

- ➢ Geometry – simplified MD
- ➢ Results

V. Conclusion

Background

- **Steam penetration into lumen is still not fully understood**
  - Influence of the geometry and material of the MD (medical device)
  - Influence of condensation & re-evaporation on the steam penetration behavior
  - Influence of the sterilization cycle (pressure curve)

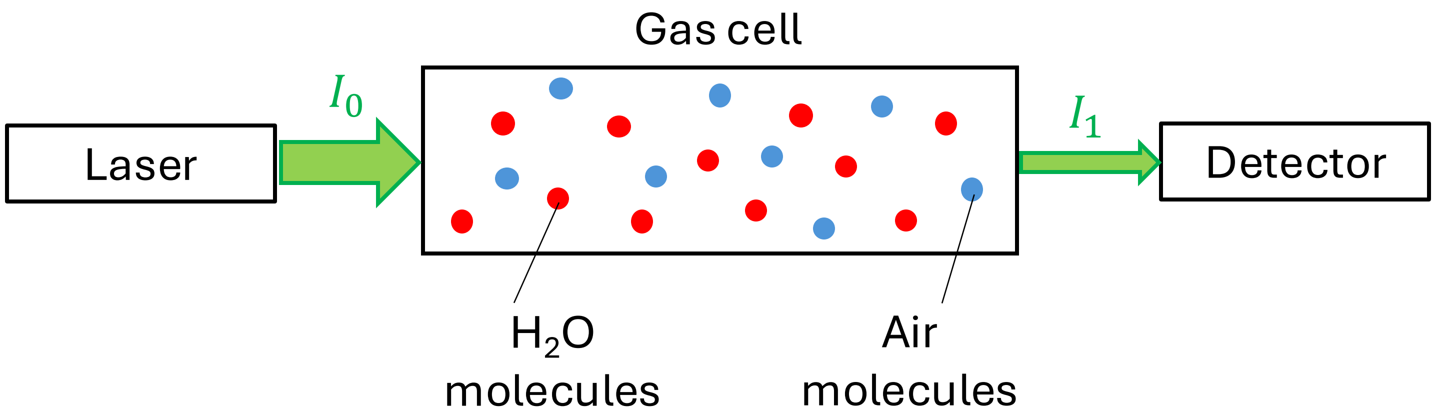


- **Monitoring currently based on CIs/BIs**
  - Feedback only after cycle completion
  - No precise quantitative data
  - → New method needed

- **Aim: improve fundamental understanding**
  - Optimize sterilization cycles
  - Support manufactures with MD designs

Absorption spectroscopy

- **Water vapor interacts with light at specific wavelengths**
  - Absorption occurs → Intensity I is reduced ($I_1 < I_0$)
- **As light source a tunable laser diode was used**
  - at a wavelength of 1364 nm
  - wavelength tuned (changed) by current and temperature
- **Photodetector measures the reduced light intensity I_1**



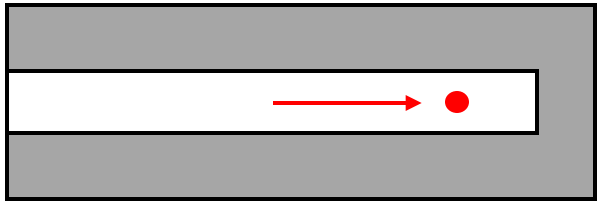
Computational fluid dynamics

What is CFD:

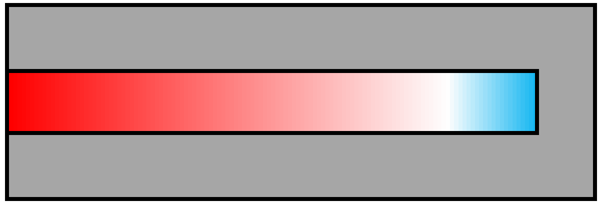
- **Powerful tool** to **simulate** the **fluid flow** (liquids & gases) of **real life applications**
  - ➢ Aerodynamics around cars, combustions processes, etc.
  - ➢ <u>Steam penetration</u> into <u>cavities</u> incl. condensation & evaporation effects

Why we use CFD in addition to experiments

dead-ended pipe



Experiment validates CFD



Experiment

- ➢ provides real data
- ➢ but only at a few points

CFD

- ➢ Information of the entire domain
- ➢ Possible to investigate complex geometries

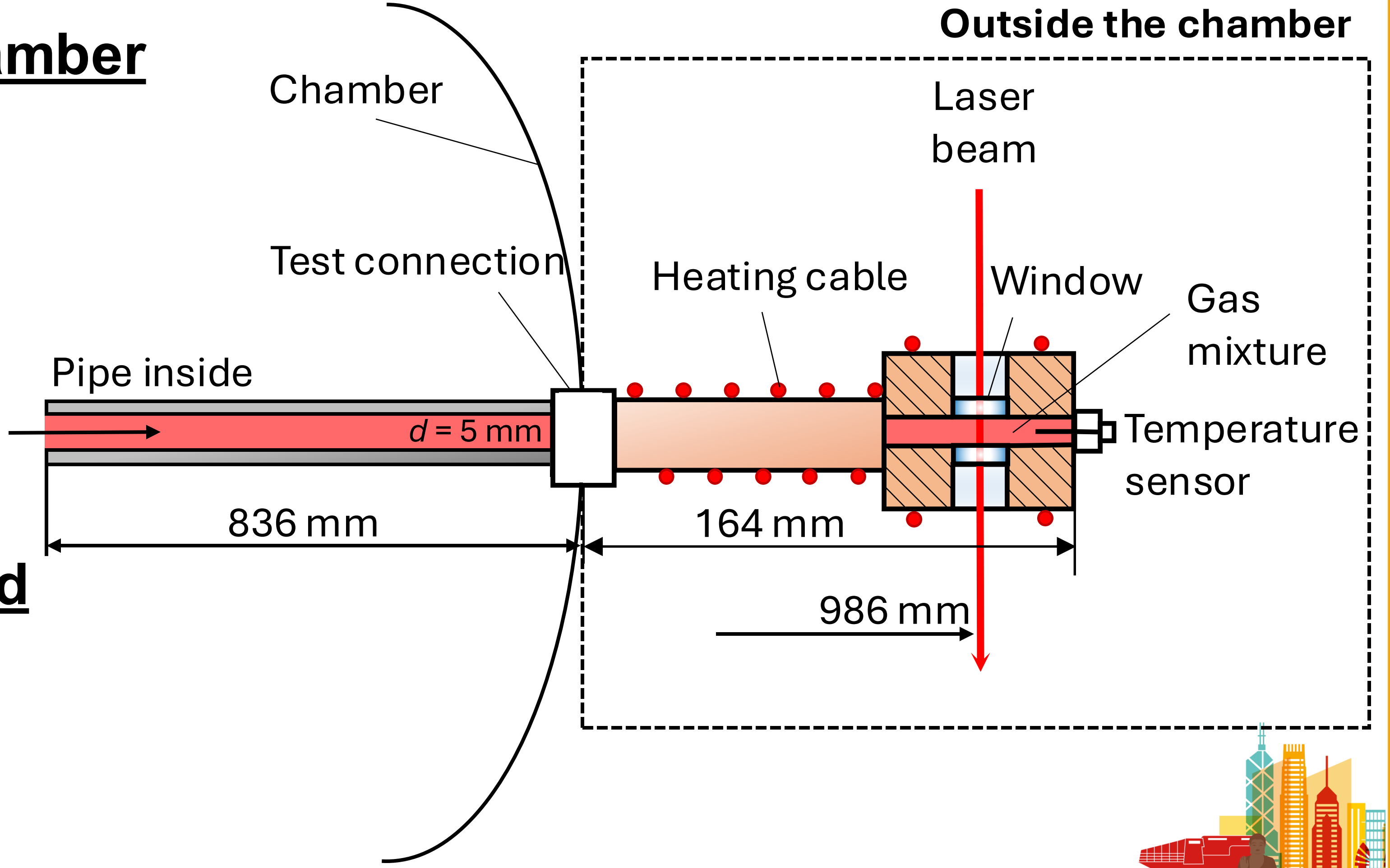
Together: Spectroscopy data ensures CFD is reliable

Steam penetration

thin-walled channels

Optical setup outside the chamber

- heated to 140 °C (avoid condensation)
- heated "pipe" outside
  - aluminum
  - 164 mm long
  - 4 mm internal diameter
- **Mountable to any autoclave** via the test connection



1 meter long pipe investigated

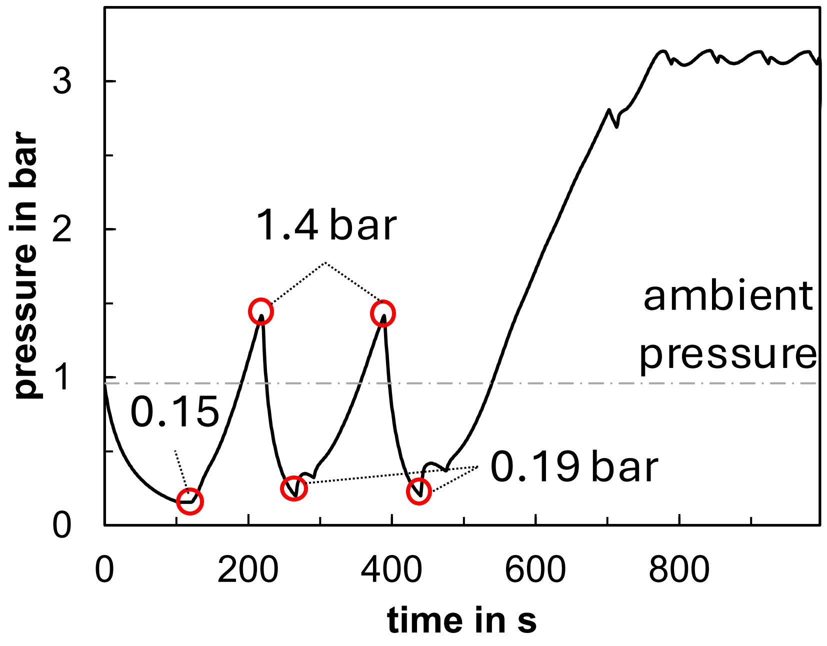
- unheated pipe inside
  - stainless steel
  - 836 mm long
  - 5 mm internal diameter
  - 0.5 mm wall thickness

Steam penetration
thin-walled channels

Sterilizer
- Table top sterilizer – 22 liter chamber

Sterilization cycle
- Universal 134 °C
- 3 vacuum phases → setpoint 0.15 bar and 0.19 bar
- 2 pulsations → setpoint 1.4 bar

CFD simulation
- only internal pipe flow
- comparison of the H_2O mole fraction



Steam penetration

thin-walled channels

Results of the 134 °C cycle

- At a depth of 986 mm

Comparison at the start of the sterilization plateau

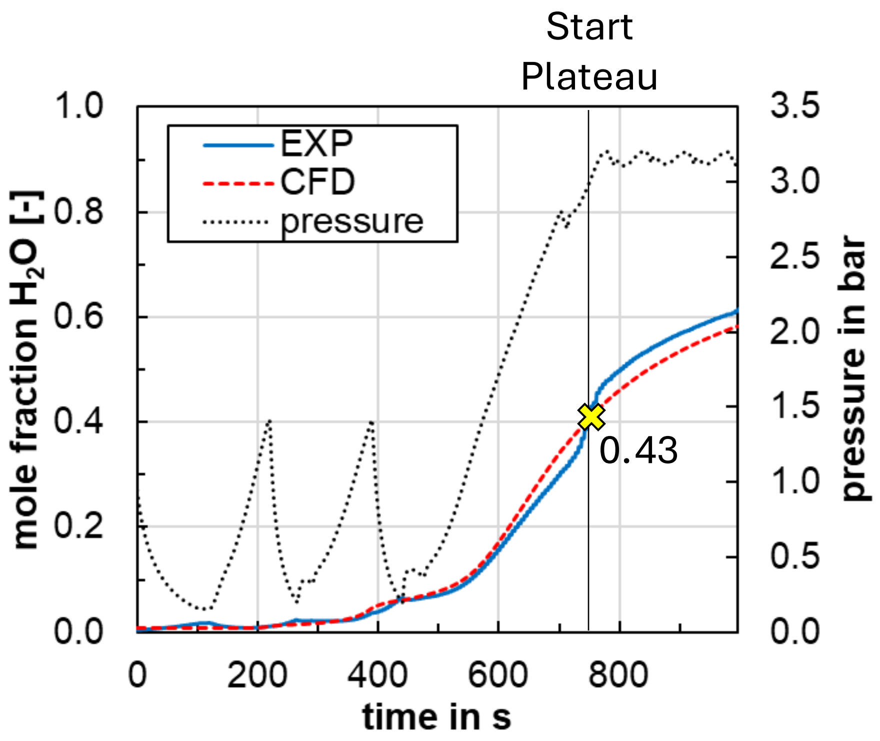
- EXP: 0.43
- CFD: 0.42

Excellent agreement between experiment and simulation

- Over the entire period

Similar low steam values also reported in:

"Steam penetration in thin-walled channels and helix shaped Process Challenge Devices", van Doornmalen et al. (2015)



Steam penetration

thin-walled channels

Possibilities to increase steam penetration

- Increase number of pulsations
- Lower vacuum set points
- Higher injection set points

Leverage molecular diffusion

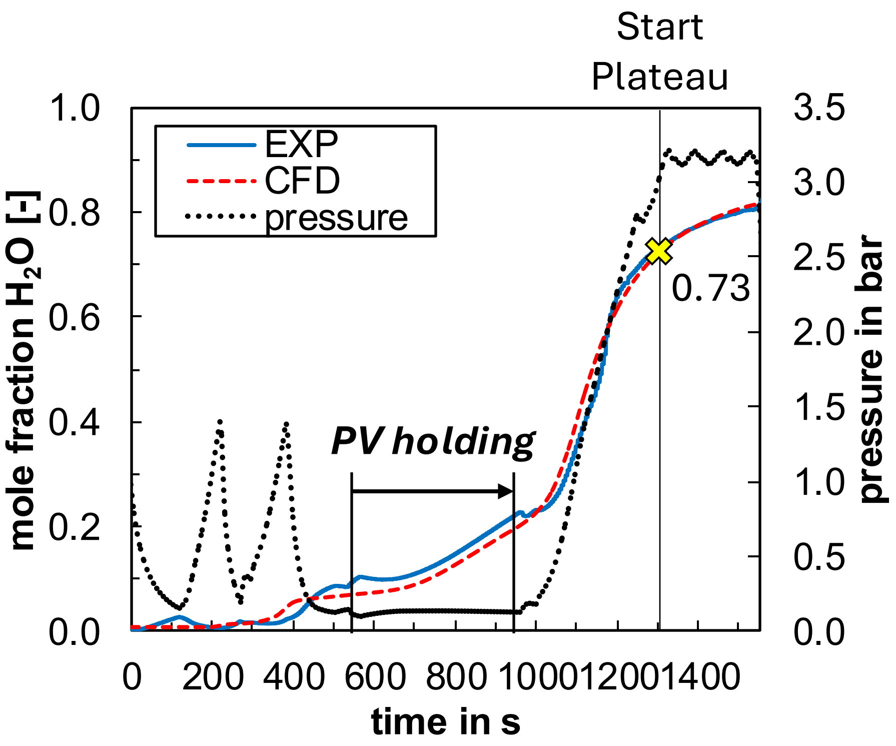
- The lower the pressure the stronger is this effect
- Similar to sterilization with hydrogen peroxide (H_2O_2)

"PV holding" phase introduced

- After the last vacuum phase
- 400 s at 0.13 bar

Steam amount increased to 0.73 (start plateau)

- Compared to 0.43 with the original cycle
- Hardly any additional water or energy required



Steam penetration

thin-walled channels

Conclusion

Successfully measured the steam amount at the end of a 1 m pipe

- High temporal resolution (when happens what)
- Quantitatively resolved

CFD model matches experimental data excellently

- Alternative cycle can be tested virtually

Steam penetration improves when adding holding phases during vacuum

- Steam amount increased from 0.43 → 0.73
- Requires almost no extra water or energy
- Trade-off: longer cycle time → “Eco-Mode”

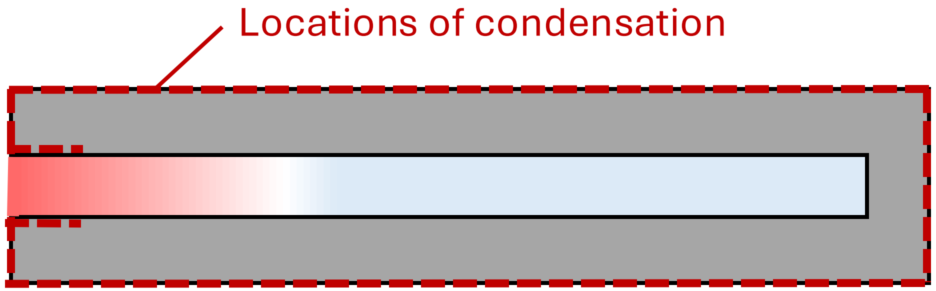
Open Question: How much steam is needed inside cavities?

- Future task: Combine our presented methods with BIs

Steam penetration
hollow devices

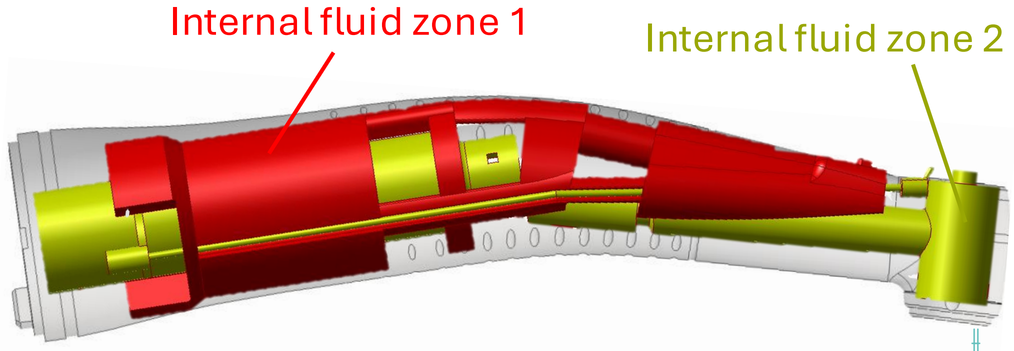
Steam penetration in thin-walled (metal) channels

- Condensation occurs mainly **outside** and slightly near the **inlet**
- **Internal surfaces** heat up quickly due to thin walls
- Internal flow depends on **pressure gradients** and **diffusion effects**
- **Phase changes** can be **neglected** in the **CFD** modeling



Steam penetration in hollow devices

- Many **internal surfaces** to reach
- **Outer walls** heat up quickly
- **Inner walls** remain cooler until steam enters
- **Steam entry is essential** to heat everything
- **NCGs + condensation/re-evaporation** strongly affect penetration



Dental handpiece

Steam penetration

hollow devices

Experiment to Validate the CFD

- Phase change strongly influences steam penetration
- Pipe around a pipe → "Double pipe"

Opening I

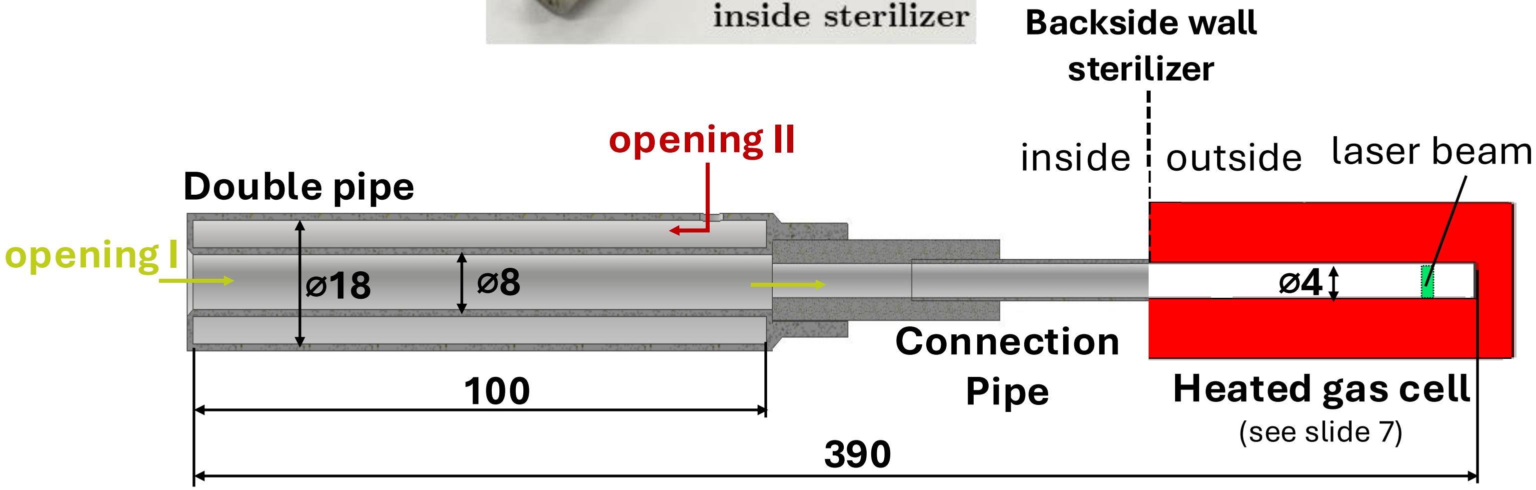
- Main path to the optical measurement

Opening II

- Intermediate volume

For the optical measurement:

- Connection pipe mounted to the double pipe
- Both inside sterilizer
- On the outside: heated gas cell
- Internal length 390 mm

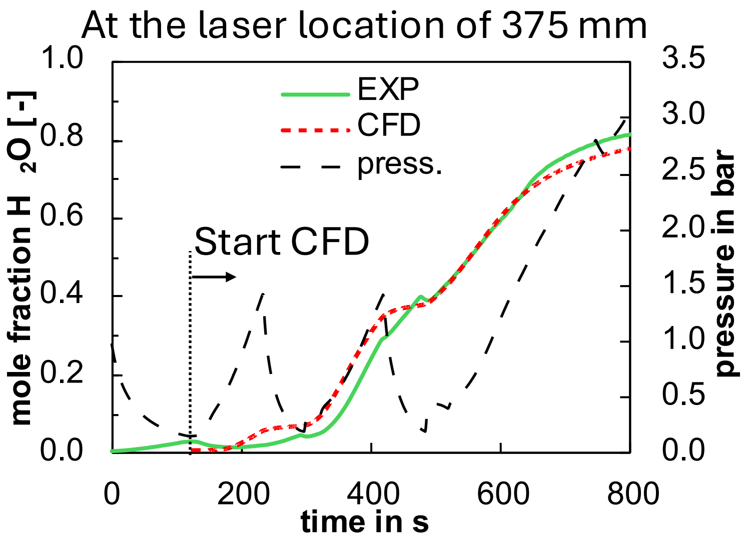


Steam penetration

hollow devices

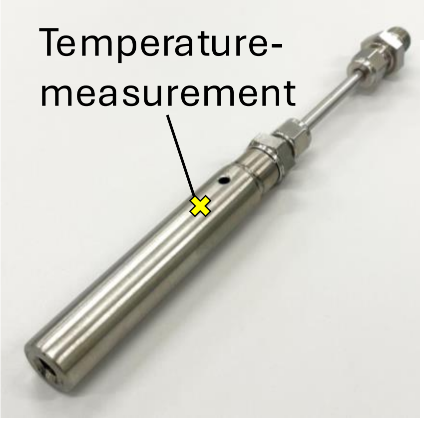
Results: steam penetration

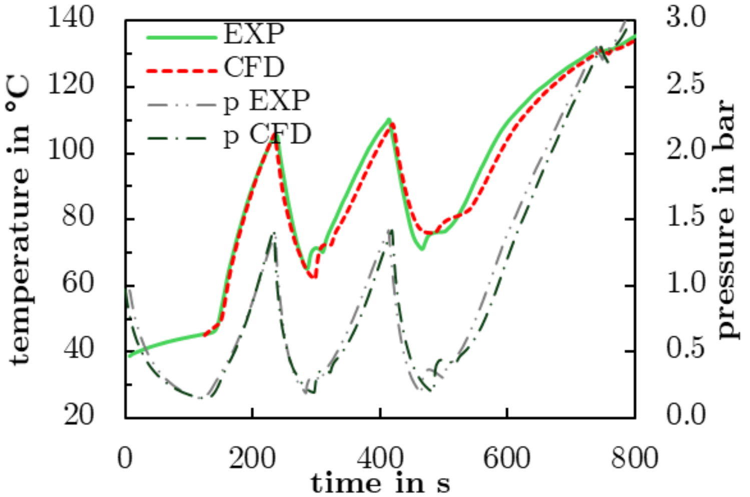
- **Excellent agreement** over the entire period
- Start of sterilization plateau (800s): **only 0.03 difference** in H_2O mole fraction



Results: temperature

- **Temperature measurement during separate cycle**
  - On the outside of the double pipe
- **Excellent agreement over the entire period**
  - Heating due to condensation
  - Cooling due to evaporation





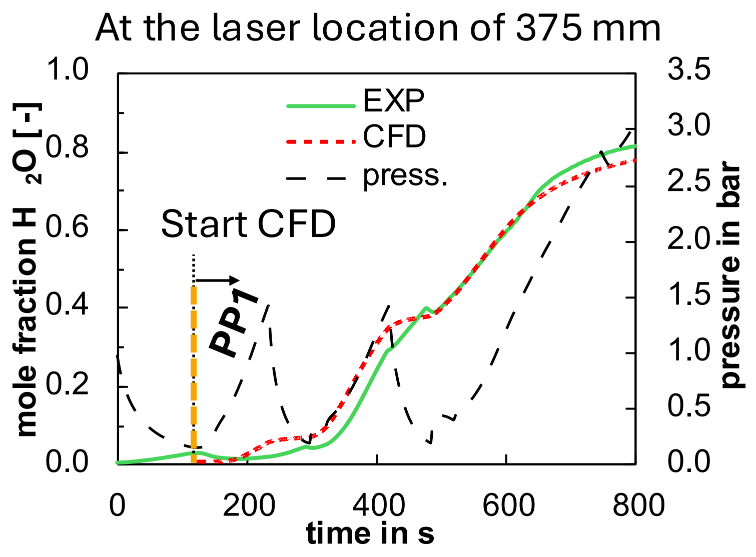
Successfully validated

Steam penetration

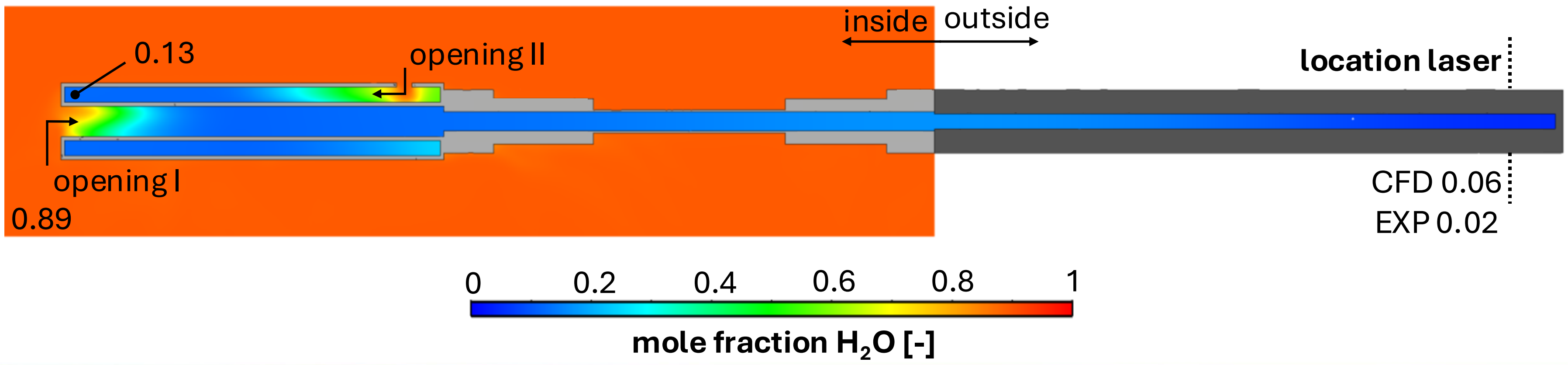
hollow devices

CFD: end PP1

- **Hardly any steam penetration occurs**
- Steam entirely **condenses** within the first **30 to 40 mm** near both openings
- Even though the **chamber environment** consists of **90 % steam**



end PP1 (t = 234 s)

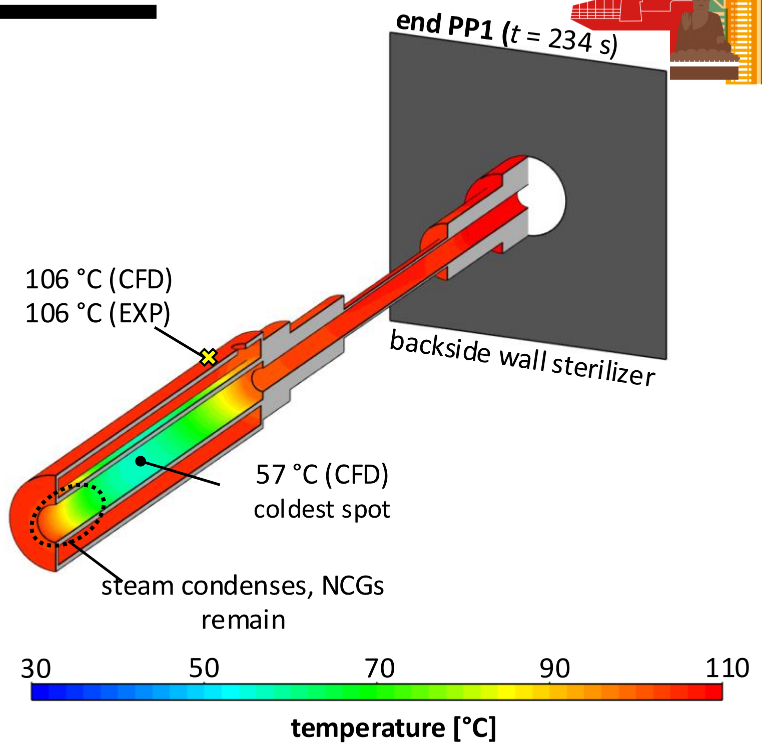


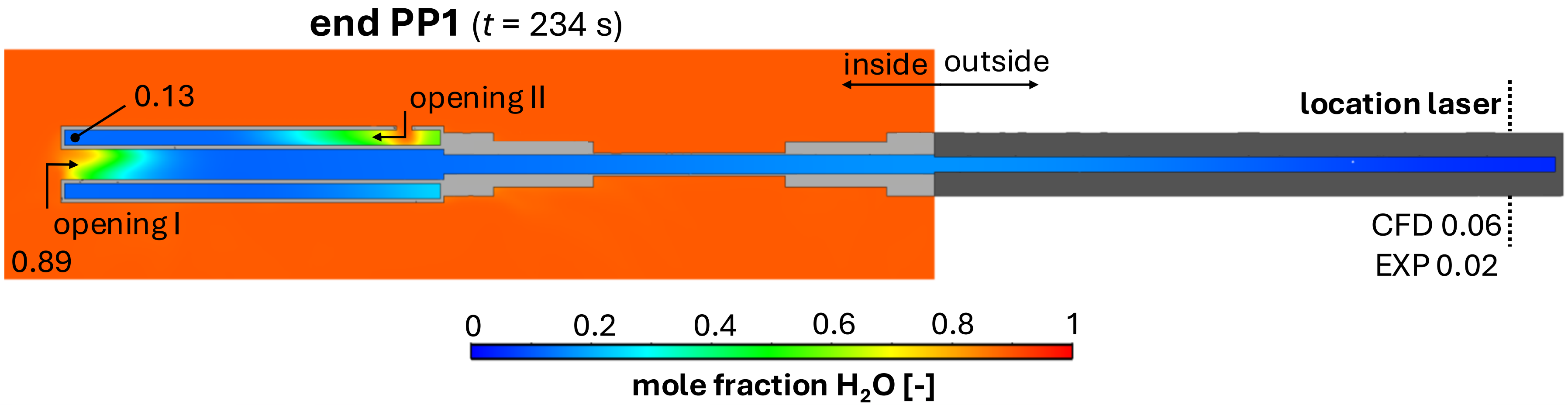
Steam penetration

hollow devices

CFD: end PP1

- **Hardly any steam penetration occurs**
- Steam entirely **condenses** within the **first 30 to 40 mm** near both openings
- Even though the **chamber environment** consists of **90 % steam**
- **Interior not well heated**
  - Coldest spot is at 57 °C



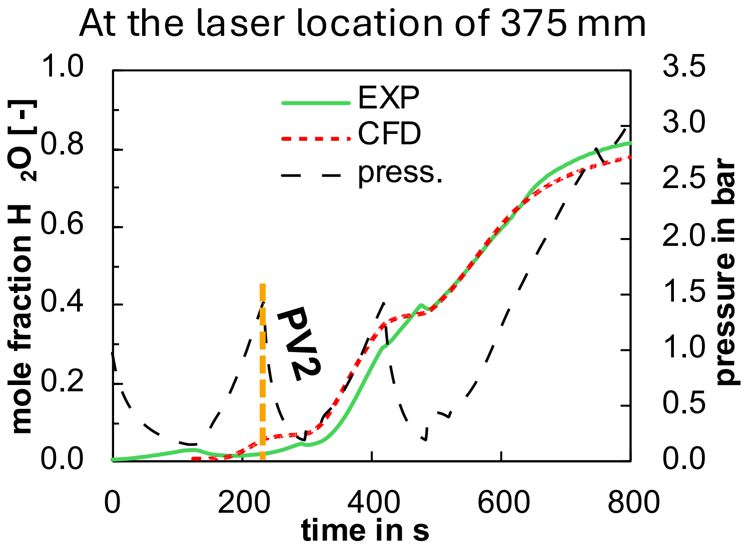


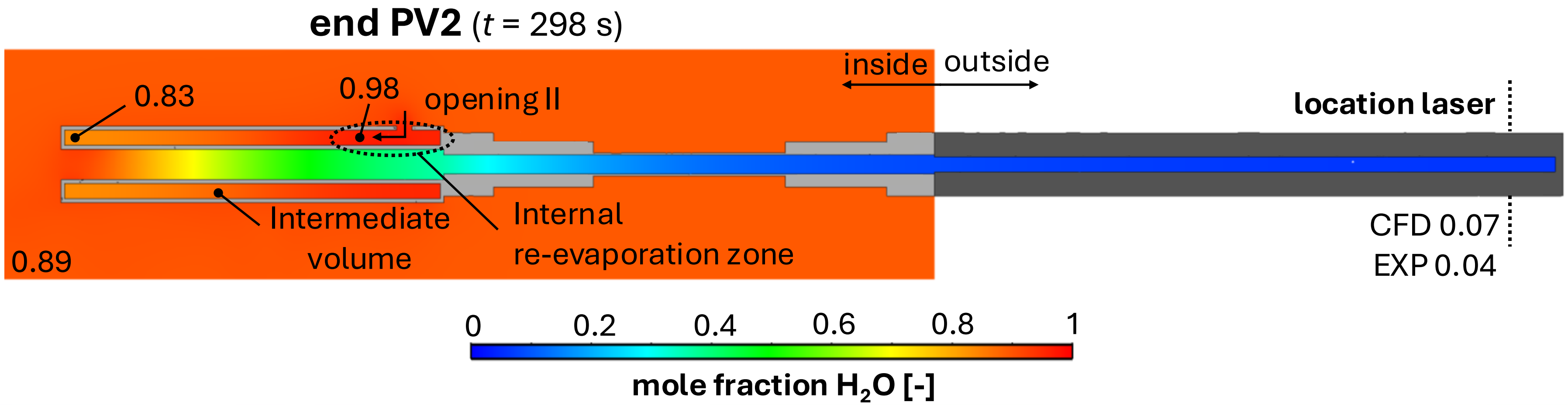
Steam penetration

hollow devices

CFD: end PV2

- **Huge increase** in **steam** mole fraction in the **intermediate volume**
  - **0.13 → 0.83** from end of **PP1** to end of **PV2**
  - Driven by **mass diffusion** and **re-evaporation** near **opening II**



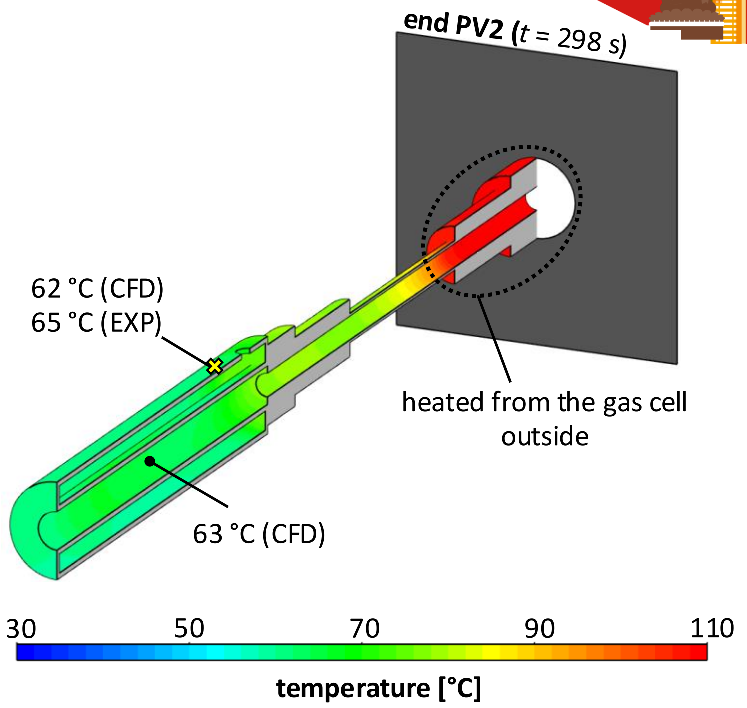


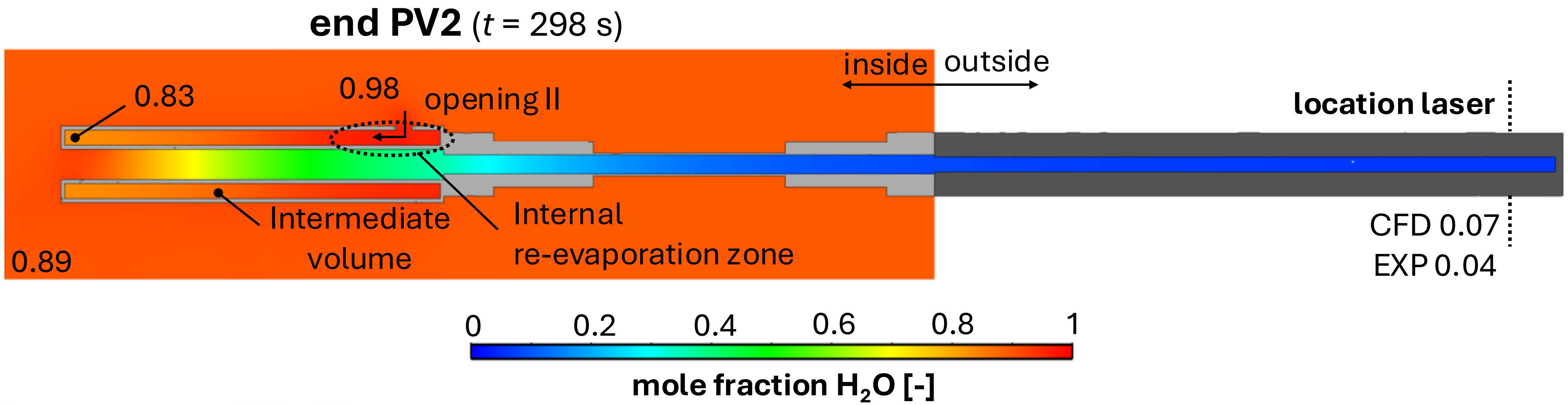
Steam penetration

hollow devices

CFD: end PV2

- **Huge increase** in **steam** mole fraction in the **intermediate volume**
  - **0.13 → 0.83** from end of **PP1** to end of **PV2**
  - Driven by **mass diffusion** and **re-evaporation** near **opening II**
- **double pipe cools** down to about **63 °C**

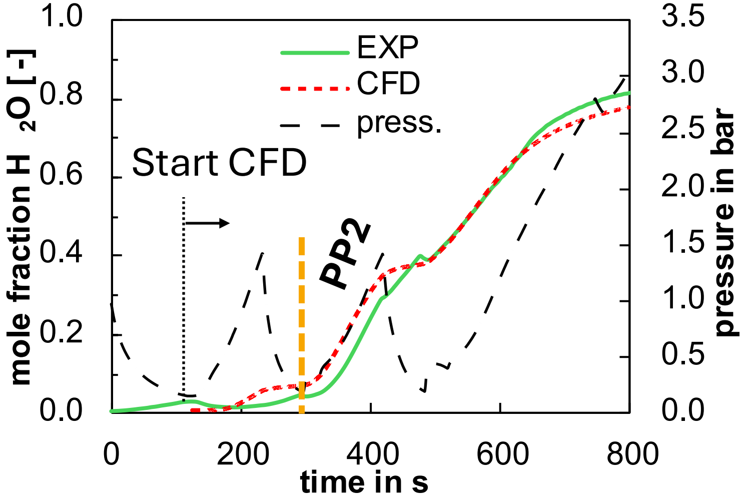




Steam penetration

hollow devices

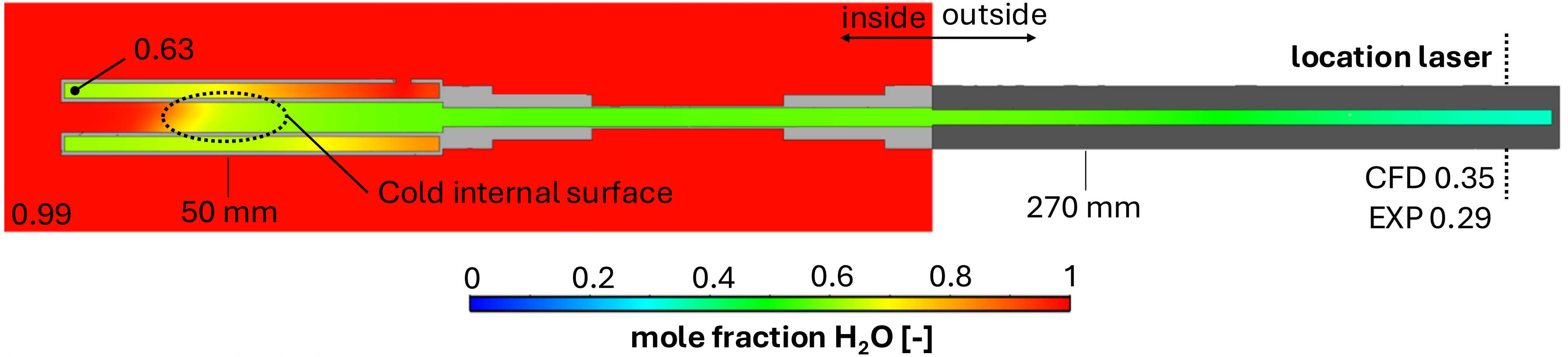
At the laser location of 375 mm



CFD: end PP2

- **Cold internal surface** acts as an **unintended filter**
  - **H_2O mole fraction** is around **0.55** between **50 mm** and **270 mm**
- **Small amounts** of **NCGs** cause this
  - About 1 % left in the chamber environment
- **Create a 100 % steam environment!!!**

end PP2 (*t* = 420 s)

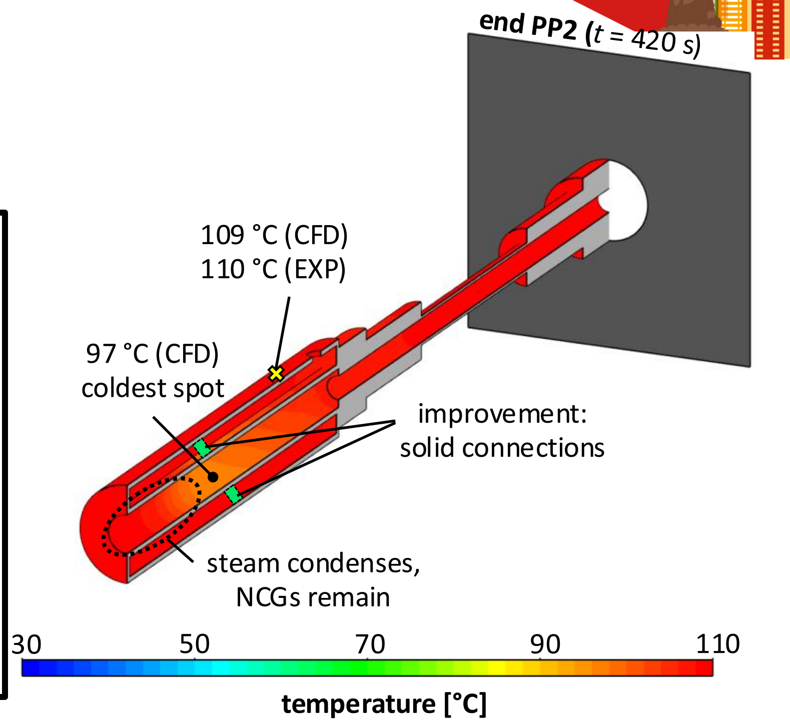


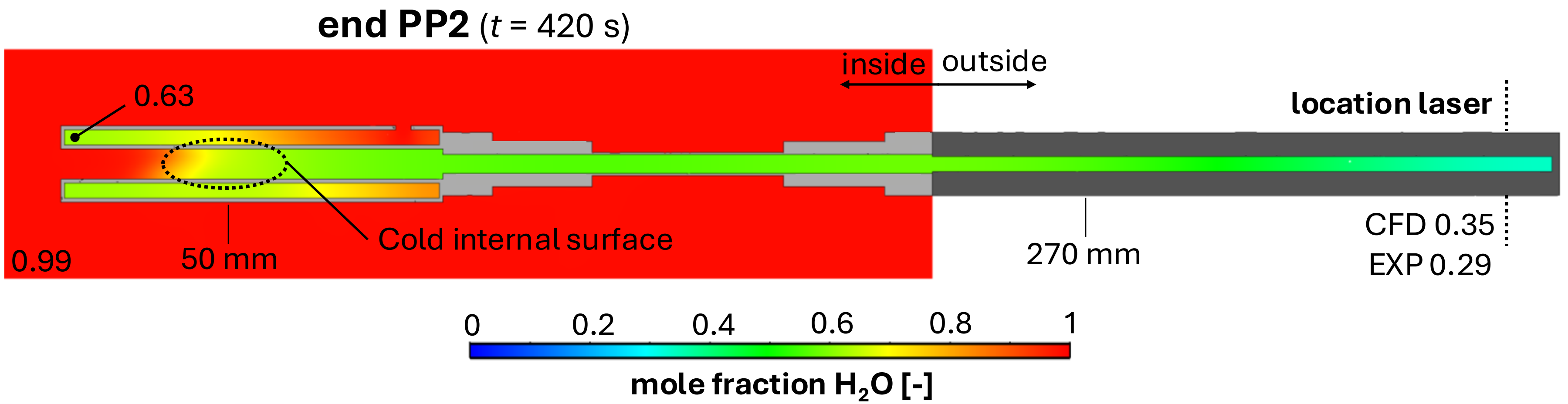
Steam penetration

hollow devices

CFD: end PP2

- **Cold internal surface** acts as an **unintended filter**
  - **H_2O mole fraction** is around **0.55** between **50 mm** and **270 mm**
- **Small amounts** of **NCGs** cause this
  - About 1 % left in the chamber environment
- **Create a 100 % steam environment!!!**
- **Connect interior** surfaces as well as possible with **exterior surfaces**
  - Heat conduction to the interior surfaces





Conclusion

- **Experiment & CFD: residual air strongly hinders steam penetration**
  - Even with **99 % steam in the chamber**, penetration into the MD failed
  - Goal: reach **100 % steam atmosphere as early as possible**
  - **Design rule**: connect internal surfaces well with external surfaces

- **CFD successfully validated with experiments**
  - Use it now for **more complex device geometries**

- **Key questions CFD can answer:**
  - Where and how much steam is present?
  - Where are the **cold spots**?
  - Is the load completely **dry** after the cycle?

Open Question: How much steam is needed inside cavities?

- If everything is at the desired sterilization temperature

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Achieving more together

I look forward to your ideas and questions

Simon Pletzer

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Related peer-reviewed publications:

- **Publication I:** *Steam penetration in long, narrow channels during steam sterilization: A combined study using wavelength modulation spectroscopy and CFD.* https://doi.org/10.1002/cite.202200135
- **Publication II:** *Modeling Steam Penetration into Hollow Devices: Effects of Phase Change and Non-Condensable Gases During Steam Sterilization.* https://doi.org/10.1016/j.ijheatmasstransfer.2023.124396